Archiving Time Table

The table below is designed to provide guidance on the minimum Sponsor/ regulatory requirements for archiving of study data for studies sponsored by University Hospitals of Leicester NHS Trust. Archiving requirements for individual studies will be reviewed and confirmed at as part of the Sponsor review.

Type of study	Retention Time Period
Clinical Trial of an Investigational medicinal product **Clinical investigation or other study of a medical device** **Combined trial of an investigational medicinal product and an investigational medicinal device.**	**Trials which are not to be used in regulatory submissions** At least five years after completion of the trial. These documents should be retained for a longer period if required by the applicable regulatory requirement(s), the sponsor or the funder of the trial **Trials to be included in regulatory submissions** The sponsor-specific essential documents should be retained for at least 25 years after completion or discontinuation of the trial or for at least two years after the last approval of a marketing application in the EU.
Clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice	Five years
Basic science study involving procedures with human subjects **Study administering questionnaires/interviews for quantitave analysis or using mixed quantitative/qualitative methodology**	Two years
Studies involving qualitative methods only **Studies limited to working with Human tissue samples(or other human biological samples)** **Studies working with data (specific project only)** **Research Tissue Banks** **Research Databases**	One year.